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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,633	12/01/2005	Pierre Roy	15675P591	7305

48329 7590 07/22/2008

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EXAMINER	
DOUKAS, MARIA E	

ART UNIT	PAPER NUMBER
4166	

MAIL DATE	DELIVERY MODE
07/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,633	ROY ET AL.	
	Examiner	Art Unit	
	MARIA E. DOUKAS	4166	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☒ Claim(s) *4-10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/15/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states,

"the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

3. The abstract of the disclosure is objected to because it includes the legal phraseology of "means for" and is not in narrative form. Correction is required. See MPEP § 608.01(b).

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

5. The disclosure is objected to because of the following informalities: Appropriate section headings have not been provided.

Appropriate correction is required.

Claim Objections

6. Claims 4-10 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4-10 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Reference to Claim 1

The applicant invokes 112, 6th paragraph with "means for releasing the active principles...," but fails to adequately describe the associated structure. There is some claim confusion as it appears that the "means for releasing" and "means for distributing" in the claim could be the same structure. On page 6, lines 26-29 of the Specification the "means for releasing" could be the microporous structure, however the "means for distributing" is also described as a microporous structure on page 4, line 22 of the Specification.

In Reference to Claim 2

Claim 2 is dependent on claim 1 which is indefinite as indicated above. Therefore, claim 2 includes all limitations recited in claim 1 and is indefinite for the reasons stated above in reference to claim 1.

In Reference to Claim 3

Claim 3 is dependent on claim 1 or 2 which is indefinite as indicated above. Therefore, claim 3 includes all limitations recited in claims 1 and 2 and is indefinite for the reasons stated above in reference to claim 1 and 2.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,186,184 to Zaffaroni (Zaffaroni). The claims have been rejected as best understood in view of the noted 112, 2nd rejection stated above.

In Reference to Claim 1

Device (Figure 1, system 10) for delivering active principles (drug 13) to the eye (col. 2, lines 45-51), comprising a reservoir (reservoir 15) able to contain the active principles (col. 5, lines 44-47), and means for releasing the active principles contained in the reservoir towards the vicinity of a site intended to receive the active principles (col. 11, lines 10-13; whereby 112, 6th paragraph is used and based on applicant's Specification page 6, lines 26-29, it implies the structure is a microporous wall), characterized in that the device also comprises means for distributing the active principles which can be driven by iontophoresis or electroporation (col. 11, lines 10-13; whereby 112, 6th paragraph is used and based on applicant's Specification page 4, line 22, the distribution means can be a microporous wall).

In Reference to Claim 2

Device according to Claim 1 (see rejection of claim 1 above), characterized in that the distribution means are a microporous wall (col. 11, lines 10-13).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni in view of U.S. Patent No. 6,154,671 to Parel (Parel).

Zaffaroni teaches the device according to Claim 1 or 2 (see rejection of claims 1 and 2 above), characterized in that the distribution means contain valves (portal 12) (col. 3, lines 60-62; col. 5, lines 1-4, lines 53-59, whereby the concentration gradient of drug across the portal enables the drug to be driven across the portal and the portal provides an exit that directs the delivery of the drug to a selected site), but fails to teach the opening of which is driven by iontophoresis or electroporation. Parel teaches an iontophoretic system (Figure 1) that is used to drive medicament from a reservoir 8 into the eye (col. 2, lines 5-20) in order to more specifically target certain tissues (col. 2, lines 48-50).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have applied the iontophoretic system of Parel to the device of Zaffaroni in order to provide additional means for driving the drug across the portal as explicitly taught by Parel.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 7,181,287 (Greenberg) teaches an implanted drug containing pillow that releases drug within the eye through osmosis or polymer degradation. U.S. Patent No. 6,442,423 (Domb) teaches an applicator with a drug loaded hydrogel that uses iontophoresis to deliver the drug to the eye. U.S. Patent No.

6,264,971 (Darougar) teaches an ocular insert that releases drug into the eye using osmosis, diffusion, bio-erosion. U.S. Patent No. 5,476,511 (Gwon) teaches a drug releasing device capable of being implanted under the conjunctiva of the eye. U.S. Patent No. 3,977,404 (Theeuwes) teaches an osmotic device to deliver an agent to the eye that has a microporous reservoir.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA E. DOUKAS whose telephone number is (571)270-5901. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ken Bomberg can be reached on (571)272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MD

/Kenneth Bomberg/

Supervisory Patent Examiner, Art Unit 4166